PROCEDURES FOR THE EVALUATION OF ESTABLISHMENT CONTROL PROGRAMS FOR *LISTERIA MONOCYTOGENES*

FSIS is conducting an evaluation of the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by establishments to control *Listeria monocytogenes* (LM) in their post-lethality exposed ready-to-eat (RTE) meat and poultry products. Results of this evaluation will be used to determine the risk of LM contamination and the frequency of risk-based verification sampling for LM.

This document includes procedures and questionnaires for evaluating an establishment's control measures for LM. The document also contains an Appendix that includes definitions, explanation of terms, and examples of validation studies with highlighted information that are important for control.

Background:

L. monocytogenes is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedures (SOP) or other prerequisite program. 9 CFR Part 430 "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products: Final Rule, June 6, 2003" with implementation starting on October 6, 2003, mandates establishment compliance with one of three post-lethality alternatives.

For establishments that produce RTE products that are post-lethality exposed, FSIS needs your assistance in providing information that will answer the following questions.

1. Has the establishment selected one of the three alternatives per 430.4(b) of the regulations?
2. For establishments electing to use Alternative 1, the following questions apply: (a) Does the establishment use a post-lethality treatment for product AND an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
3. For establishments electing to use Alternative 2, the following questions apply: (a) Does the establishment use a post-lethality treatment for product OR an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
4. For establishments electing to use Alternative 3, the following questions apply: (a) Does the establishment have a sanitation program that addresses testing of food contact surfaces: How effective is that program?

You will evaluate the establishment's level of effectiveness in implementing Alternatives 1, 2 and 3 through a set of questions for each Alternative. The set of questions for each Alternative are provided in separate Evaluation Sections in the Procedures. The Evaluation Sections are numbered I, II, III and IV. Step 4 in the **Instructions** matches each Alternative with the appropriate Evaluation Sections.

INSTRUCTIONS

(If you have any questions regarding this survey, please contact Amelia K. Sharar (202-205-0009, Amelia.Sharar@FSIS.USDA.gov) or Paul Uhler (202-205-0438, Paul.Uhler@FSIS.USDA.gov)

Step 1:

- Have the following documents ready and available for review: the establishment's HACCP plan, Sanitation SOP, and prerequisite programs addressing post-lethality exposed RTE product associated with 9 CFR 430.
- Use the establishment's completed FSIS Form 10, 240-1 as reference ONLY. Do not simply re-state what is on the form.
- For determination of risk-based verification testing, FSIS needs to have this evaluation completed without participation of establishment personnel. All information needed should be readily available for review, in accordance with HACCP requirements. FSIS will follow-up in circumstances in which there are significant discrepancies between these procedures and the information provided by the establishment on FSIS Form 10,240-1. (*NOTE: FSIS is not asking the establishment personnel to participate by responding to the checklist questions because FSIS has not sought approval from OMB to conduct such information gathering from industry. However, FSIS does have authority to assess and document the information relative to the checklist that is available as part of the establishment's food safety system FSIS can share with the establishment the checklist and the FSIS assessment that was completed as part of the checklist.)*

Products within the same HACCP process category and HACCP plan are controlled in the same manner for LM. Group the products that are controlled by the same Alternative and treatment. Use separate evaluation forms for products or product groups with unique situations, such as the same alternative and treatment but have different methods/sources of validation or have different log reduction or suppression. For example, for the same product in Alternative 2 using AMAP and the same antimicrobial agent used, such as hotdog treated with sodium lactate validated by a challenge study, and hotdog treated with sodium lactate validated using a modeling program, separate evaluation forms should be used. You will conduct one evaluation for each product group, using the questions in the appropriate Evaluation Sections for that group's Alternative (See Step 4 Instructions). Include the name of each product within the group in the entry for product name in the Preliminary Questions section. Complete as many Evaluation Sections to cover all products produced by the establishment that are associated with 9 CFR 430.

Step 2: Answer preliminary questions in "Guide to Selecting Evaluation Sections."

Step 3: Read through the evaluation sections and accompanying tables prior to completing the preliminary question related to the control programs for each applicable product(s):

Section I: Post-lethality Treatment (PLT)
Section II: Antimicrobial Agent or Process (AMAP)
Section III: Sanitation Program
Section IV: On-going Verification

Step 4: For each Alternative, use the following sections to score the evaluation of that control program:
Alternative 1, use Section I, II, III and IV
Alternative 2 (PLT), use Section I, III and IV
Alternative 2 (AMAP), use Section II, III and IV
Alternative 3, Section III and IV

Step 5: Follow the instructions provided on how to score the establishment's validation and on-going verification documentation in your assessment for each product.

GUIDE TO SELECTING EVALUATION SECTION

PRELIMINARY QUESTIONS

Establishment Number: _____

1. Does the establishment produce post-lethality exposed ready-to-eat product covered by 9 CFR 430?

   ☐ YES

   ☐ NO (STOP, product is not covered by 9 CFR 430)
2. Did the establishment develop control measures that meet one of the three Alternatives for the product, as required in 9 CFR 430.4?

   ☐ YES

   ☐ NO (STOP and consult with front-line supervisor)
3. In the chart below, list the products covered by 9 CFR 430 and the Alternative chosen by the establishment.
   NOTE: There can be only one Alternative chosen for each product group. If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430.

PRODUCT(GROUP) NAME	ALTERNATIVE

4. Complete the sections that correspond to the chosen alternative.

Alternative 1 (PLT and AMAP)	Sections I, II, III and IV
Alternative 2 (PLT only)	Sections I, III and IV
Alternative 2 (AMAP only)	Sections II, III, and IV
Alternative 3 (Sanitation)	Sections III and IV

SECTION I – Post-Lethality Treatment (PLT)

Product (Group) Name: _____
Post-lethality Treatment used: _____

For the following questions, please place an X in the appropriate response column.
(NOTE: If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Score responses using the scoring instructions at the end of these questions.)

Questions	Yes	No	Not Sure	N/A
1. Is the post-lethality treatment validated and documented? (*Note: See APPENDIX for examples of validation.*)				
2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? (*Note: Examples of validation methods that can be used are challenge study for the product, published study, modeling program.)*				
3. If the critical variables have been identified for PLT, are they being applied in the HACCP plan in a similar manner?				
4. Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the PLT?				
5. Is the establishment using the PLT as described in the validation with regards to equipment and procedures?				
6. If the critical variables, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? *(Note: Place an X on N/A if you answered "YES" to questions 2-5)*				
7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the PLT is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? *(Note: Place an X on N/A if you answered "YES" to questions 2-5)*				
8. Did the establishment conduct an initial validation to test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions as stated in the HACCP plan? (*This would be evident by data to demonstrate that the CCP was applied and the process was tested, e.g., product was tested prior to the treatment for presence/absence, and/or level of LM, and tested after the treatment for the same attributes in order to find low level of LM contamination using appropriate number of tests from randomly selected samples. Reliance only on tests with negative*				

Questions	Yes	No	Not Sure	N/A
results after treatment is not considered product validation and should be marked as 'No'- not validated.)				
9. Does the establishment have a rational basis or data to show that the reduction of LM by the PLT as described is sufficient to control the level of contamination of LM that may occur in the product? *(Example: evidence of actual reduction of LM contamination on product by PLT vs. level of contamination on food contact surface)*				
10. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? *(Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.)*				
11. Is the PLT treatment a pre-packaging treatment, i.e., the PLT is applied after environmental exposure but before re-packaging (e.g., infra-red treatment)? *(Note: If No, stop and score this section)*				
12. If the PLT is a pre-packaging PLT, does the establishment have validated control measures in place to prevent recontamination after treatment and before re-packaging? (*Examples of control measures are: 1) aseptic packaging procedures; 2) packaging equipment located right after the PLT equipment; 3) use of antimicrobials; 4) positive air flow; 5) other environmental control program.*)				

You have completed this section. Please score this section.

Scoring:
Conclusive: Answered 'yes' for #1-5, 8-10, and 12 if 'yes' to 11
Substantiated: Answered 'yes' to #1-3 and [6 or 7], [8 or 9], and 12 if 'yes' to 11
Inconclusive: Answered 'no' or 'not sure' to any of the following #1- 3, [6 or 7], [8 or 9] and 12 if 'yes' to 11,

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment PLT in Table 1.

Table 1: Features of a Validated Post-lethality Treatment

Table 1 gives numerical scores based on the method of validation and the log reduction achieved by the PLT. The more rigorous the validation method and the log reduction achieved by the PLT, the lower the risk, and the higher the scores. The risk of LM contamination goes down as the score goes from inconclusive to conclusive**.**

Using the result from Section I, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment's PLT as documented in its HACCP plan was derived from a manufacturer challenge study and achieves 2 log reduction of LM, and the result from SECTION I is Conclusive, circle the score provided on the appropriate row (manufacturer challenge study and equal to or greater than 2 log reduction), which in this case is 10.

Control measure	Feature	Criteria[1]	Inconclusive	Substantiated	Conclusive
Post-lethality treatment	Challenge study for the product conducted by establishment or manufacturer	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(3)	(5)
		Equal to or greater than 2 log reduction	(0)	(5)	(10)
	Published challenge study	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(2)	(4)
		Equal to or greater than 2 log reduction	(0)	(4)	(8)
	Modeling Program	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(1)	(3)
		Equal to or greater than 2 log reduction	(0)	(3)	(7)

[1] Criteria: Log reduction of *Listeria monocytogenes* (Lm)

SECTION II- Antimicrobial Agent or Process (AMAP)

Product (Group) Name: _____
Antimicrobial Agent or Process Used: _____

For the following questions, please place an X in the appropriate response column.
(NOTE: For products using intrinsic characteristics (pH below 4.39, freezing below -0.4º C (31.3º F), or water activity below 0.92), skip questions 3-8. Also, if needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Score your responses using the scoring instructions at the end of these questions.)

Questions	Yes	No	Not Sure	N/A
1. Is the AMAP validated or tested, with documentation on file? (*Examples: challenge study, published study, modeling program. See Appendix) (Note: Select "YES" if intrinsic characteristics such as freezing below -0.4º C (31.3º F), water activity below 0.92, or pH below 4.39 are used.)*				
2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, moisture, pH, water activity, etc.) used in the validation? (*Note: Examples of validation sources or documentation that can be used are challenge study for the product, published study, modeling program, intrinsic characteristics.)*				
3. If the critical variables have been identified, are they being applied in the application of the AMAP in the product?				
4. Is the establishment using the AMAP as described in the validation with regards to equipment and procedures?				
5. Is the product formulation used by the establishment the same or similar to the product or product formulation used in the validation study using the AMAP?				
6. If the critical variables, product formulation, procedures or equipment used by the establishment are not exactly the same as those used in the validation, did the establishment conduct additional validation that demonstrated that the changes are effective? (*Note: Place an X on N/A if you answered "YES" to questions 2-5.*)				
7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the treatment is effective and have the same impact even though the critical variables, product formulation, procedure or equipment are different? (*Note: Place an X on N/A if you answered "YES" to questions 2-5.*)				
8. Did the validation include a shelf life study, i.e., determining the growth of LM during storage?				

Questions	Yes	No	Not Sure	N/A
9. Is the refrigerated shelf life (use by date on the label) shorter or the same as the recommended shelf life in the validation? *Note: Place an X on N/A if no shelf life on label.*				
10. Did the establishment initially test for the adequacy of the AMAP in inhibiting LM growth? (*Example*: *product was tested prior to the treatment for level of LM, and tested after the treatment and during the shelf life for the same attributes in order to find low level of growth during shelf life using appropriate number of tests from randomly selected samples.*)				
11. Does the establishment have a rational basis or data to show that the level of growth allowed by the AMAP is sufficient to control LM growth in the product? *(Example: evidence of actual inhibition of LM growth on product by AMAP vs. level of contamination on food contact surface)*				
12. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? *(Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.)*				

You have completed this section. Please score this section.

Scoring:
Conclusive: Answered 'yes' to #1-5, 8-11. For products using intrinsic characteristics (freezing, pH, water activity), 'yes' answers to #1- 2, 10-11.
Substantiated: Answered 'yes' to #1 and [5 or 6], and 8. For products using intrinsic characteristics, 'yes' to #1- 2 and [10 or 11].
Inconclusive: Answers with 'no' or 'not sure' to any of the following: #1, [6 or 7], and 8. For products using intrinsic characteristics, 'no' or 'not sure' answers to #1- 2 [10 or 11].

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment AMAP in Table 2.

Table 2. Features of an Effective Antimicrobial Agent/Process

This table gives numerical scores based on the method of validation and the log growth allowed by the AMAP. The more rigorous the validation method or the effectiveness and the lower the log growth allowed by the AMAP, the lower the risk, and the higher the scores.

Using the result from Section II, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment's AMAP as documented in its control program is from a published study and allows 1 log growth of LM during the refrigerated shelf life, and the result from SECTION II is Substantiated, circle the score provided on the appropriate row (published study and 1 log growth),which in this case is 4.

Table 2

Control Measure	Feature	Criteria[1]	Inconclusive	Substantiated	Conclusive
Antimicrobial growth suppressing agent or process	Shelf-life study of the product using the antimicrobial agent or process	Less than or equal to 1 log	(0)	(5)	(10)
		More than 1 log but not more than 2 log	(0)	(3)	(5)
		More than 2 log	(0)	(0)	(0)
	Modeling program specific to the AMAP used in the product (e.g. Purac)	Less than or equal to 1 log	(0)	(5)	(10)
		More than 1 log but not more than 2 log	(0)	(3)	(5)
		More than 2 log	(0)	(0)	(0)
	Published study using an antimicrobial agent	Less than or equal to 1 log	(0)	(4)	(8)
		More than 1 log but not more than 2 log	(0)	(2)	(4)
		More than 2 log	(0)	(0)	(0)
	Intrinsic product characteristic	Frozen at <-4° C (31.3° F)	(0)	(5)	(10)
		Aw < 0.92	(0)	(5)	(10)
		pH < 4.39	(0)	(5)	(10)

[1] Criteria: Log growth of *Listeria monocytogenes* (Lm)

SECTION III- Sanitation Program

Product (Group) Name: _____

For the following questions, please place an X in the appropriate response column. Please note that the "N/A" response only applies to certain questions.

(NOTE: Review establishment Sanitation program or prerequisite program for the sanitation procedures used and the food contact surface (FCS) testing program (testing frequency, number of sites, hold and test, etc). If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430). Score responses using the scoring instructions at the end of these questions.)

A. Sanitation Procedures

Questions	Yes	No	Not Sure	N/A
1. Are employee hygiene procedures available in a written document?				
2. Are employees trained in hygiene procedures?				
3. Are gloves used properly (e.g., are they disposed of when leaving processing line and when touching anything other than product or food contact surface)?				
4. Are outer garments removed when leaving RTE area?				
5. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work?				
6. Are food and operator hand tools stored in a sanitary manner?				
7. Are traffic patterns established to eliminate movement of personnel between the raw and RTE areas?				
8. Are traffic patterns established to eliminate movement of equipment between the raw and RTE areas?				
9. Is traffic into RTE areas controlled to prevent contamination?				
10. Are the raw and RTE areas physically separated (e.g., by a wall, etc.)?				
11. If raw and RTE areas are not physically separated, is the potential for cross contamination minimized? *(Note: If 'yes' to question 10 above, place an X on N/A.)*				
12. Are different utensils used in the raw and RTE areas?				
13. If different utensils are not used, are utensils washed and sanitized between raw and RTE processing? *(Note: If 'yes' to question 12 above, place an X on N/A.)*				

Questions	Yes	No	Not Sure	N/A
14. Are garments worn in RTE areas readily distinguished from those used in the raw areas?				
15. Are maintenance employees restricted from the RTE areas during operation or are hygienic practices followed if access is needed during operation?				
16. Do tools and equipment for maintenance used in the RTE area remain in the RTE area?				
17. Are the thermometers, maintenance tools and equipment cleaned and sanitized before use?				
18. Are all materials for discard (trash and waste) removed at clean up (mid-shift, end-shift, etc.)?				
19. Is equipment cleaned at the end of operation to remove food and other debris? *(Note: In establishments conducting extended operations, clean-up operations may occur at a frequency of less than daily.)*				
20. Is equipment such as slicers and dicers with blades disassembled for thorough cleaning at the end of the operation*? (Note: If slicers or dicers are not used, place an X on N/A.)*				
21. Are equipment and floors sanitized after being rinsed?				
22. Is sanitizer for equipment and floors used in the concentration specified where used?				
23. Are operations discontinued during construction, or are the areas under construction or remodeling isolated to prevent contamination of other areas of operation? *(Note: Place an X on N/A only if there is no construction.)*				

B. Sanitation Testing

Questions	Yes	No	Not Sure	N/A
1. Does the sanitation program provide for testing FCS in the post-lethality processing environment?				
2. Does the sanitation program identify the conditions under which the establishment will implement hold-and-test procedures following a FCS test that is positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
3. Does the sanitation program state the frequency for testing?				
4. Does the sanitation program or other recordkeeping system identify the location of sites for sampling?				
5. Does the sanitation program identify the size of sites for sampling?				

Questions	Yes	No	Not Sure	N/A
6. Are the locations of the sites chosen randomly?				
7. Is the size of the sampling area at least 1-square foot if surface allows?				
8. Are all possible FCS sampling sites identified?				
9. Does the sanitation program explain why the testing frequency is sufficient to ensure effective control of *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
10. If a FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were the hold-and-test procedures implemented as written in the sanitation program? *(Note: If FCS tested negative, place an X on N/A.)*				
11. If FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were measures taken to prevent recurrence? *(Note: If FCS tested negative, place an X on N/A.)*				
12. If FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were corrective actions taken to identify and eliminate the source of contamination? *(Note: If FCS tested negative, place an X on N/A.)*				
13. If a FCS tested positive for *L. monocytogenes*, was the lot of product affected destroyed or reworked with a process that eliminates *L. monocytogenes*? *(Note: If FCS tested negative, place an X on N/A.)*				
14. Were the results of the product testing documented?				
15. Were non-FCS tested for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
16. Was follow up testing conducted on all non-FCS that tested positive for *Listeria*-like, *Listeria* spp. or *L. monocytogenes*? *(Note: Place an X on N/A only if there is no positive follow-up non-FCS test.)*				

Complete the next table only for an establishment that produces deli or hotdog product in Alternative 3. *(Questions reflect regulatory requirements for these products.)*

Questions	Yes	No	Not Sure	N/A
17. Was follow-up testing conducted on the FCS site that tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes* to verify that the corrective actions after an initial positive test on a FCS were effective? *Note: Place an X on N/A only if there is no positive follow-up FCS test.*				
18. Was follow-up testing conducted on the FCS area surrounding the FCS site that tested positive for *Listeria*-like,				

Questions	Yes	No	Not Sure	N/A
Listeria spp., or *L. monocytogenes* to verify that the corrective actions after an initial positive test on a FCS were effective? *Note: Place an X on N/A <u>only</u> if there is no positive follow-up FCS test.*				
19. If a second follow-up FCS tested positive for *Listeria*-like or *Listeria* spp. on follow-up testing, were lots of affected product held? *Note: Place an X on N/A <u>only</u> if there is no second follow-up positive FCS test.*				
20. If the second follow-up FCS tested positive for *Listeria*-like, *Listeria* spp. on follow-up testing, were the affected lots of product tested for *Listeria*-like, *Listeria* spp. or *L. monocytogenes*? *Note: Place an X on N/A <u>only</u> if there is no second follow-up positive FCS test.*				
21. If a second follow-up FCS tested positive for *L. monocytogenes* on follow-up testing, were the affected lots of product destroyed or reworked with a process that is destructive of *L. monocytogenes*? *Note: Place an X on N/A <u>only</u> if there is no second follow-up positive FCS test.*				
22. If the second follow-up FCS tested positive for *Listeria*-like or *Listeria* spp. on follow-up testing, did the sampling method and frequency provide a level of statistical confidence that ensured that each lot was not adulterated with *L. monocytogenes?* (e.g., is the sampling method and frequency based on a statistical sampling plan such as the ICMSF) *Note: Place an X on N/A <u>only</u> if there is no second follow-up positive FCS test.*				

<u>You have completed this section. Please score this section.</u>

Scoring:

Conclusive: For **all establishments producing deli or hot dog products** under Alternative 3: Answered **"Yes"** or "N/A" to **all questions** in **A. Sanitation Procedures and** in **B. Sanitation Testing**.

For all other establishments producing **products under Alternative 1 or Alternative 2** or **non-deli or non-hotdog products under Alternative 3**: Answered **"Yes"** or "N/A" to **all questions** in section **A. and 1-16** in **section B.**

Substantiated: All establishments answered **"Yes"** or "N/A" **to at least 18 of the 23 questions** under **A. Sanitation Procedures**.

For **all establishments producing deli or hot dog products** under Alternative 3: Answered **"Yes"** or "N/A" to questions 1- 22 except **6, 7, 8, 15 and 16** in **section B**.

For all other establishments producing **products under Alternative 1 or Alternative 2** or **non-deli or non-hotdog products under Alternative 3**: Answered **"Yes"** or "N/A" to **questions 1- 14 except 6, 7, and 8** in **section B.**

Inconclusive: All establishments answered **"Yes" or "N/A"** to less than **18 of the 23 questions** in **A. Sanitation Procedures**.

For **all establishments producing deli or hot dog products** under Alternative 3: Answered **"No"** to any question 1- 22 **excluding 6, 7, 8, 15 and 16** in **section B**.

For all other establishments producing **products under Alternative 1 or Alternative 2** or **non-deli or non-hotdog products under Alternative 3**: Answered **"No"** to any **questions 1- 14 excluding 6, 7, 8** in **section B.**

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment sanitation criteria in Table 3.

Table 3. Features of a Sanitation Program

Table 3 gives the numerical scores based on the rigor of the testing. Higher frequency of testing suggests more rigorous control, lower risk, and higher scores. These scores will be used in the risk-based verification model.

Using the result from Section II, circle the score provided (in parenthesis) for the appropriate criteria. To obtain the score, apply the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to the applicable establishment sanitation control program listed in Table 3. For example, if the establishment's FCS testing is 1/line/month for Alternative 3 as documented in its control program and the result from the SECTION III was substantiated, circle the value in the space provided in the appropriate row, which is 3 in this example.

Control Measure	Feature	Criteria	Inconclusive	Substantiated	Conclusive
Sanitation	FCS testing frequency	Alt 1 (AMAP & PLT) <1/line/6 month	(0)	(1)	(2)
		Alt 1 (AMAP & PLT) 1/line/6 month	(0)	(4)	(6)
		Alt 1 (AMAP & PLT) >1/line/6 month	(0)	(7)	(10)
		Alt2 (AMAP or PLT): <1/line/3month	(0)	(0)	(0)
		Alt2 (AMAP or PLT): = 1/line/3month	(0)	(3)	(5)
		Alt2 (AMAP or PLT): >1/line/3month	(0)	(5)	(10)
		Alt 3: <1/line/month (non-deli, non-hotdog, or v sm. vol. deli or hotdog)	(0)	(0)	(0)
		Alt 3: = 1/line/month (non-deli, non- hotdog, or v sm. vol. deli or hotdog)	(0)	(3)	(5)
		Alt 3: >1/line/month (non-deli, non- hotdog, or v sm. vol. deli or hotdog)	(0)	(5)	(10)
		Alt 3: <2/line/month (sm. vol., deli or hotdog)	(0)	(0)	(0)
		Alt 3: =2/line/month (sm. vol., deli or hotdog)	(0)	(3)	(5)
		Alt 3: >2/line/month (sm. vol. deli or hot dog)	(0)	(5)	(10)
		Alt 3: <4/line/month (lg. vol., deli or hotdog)	(0)	(0)	(0)
		Alt 3: =4/line/month (lg. vol., deli or hotdog)	(0)	(3)	(5)
		Alt 3: >4/line/month (lg. vol., deli or hotdog)	(0)	(5)	(10)

SECTION IV- On-Going Verification System

Product (Group) Name _____

For the following questions, please place an X in the appropriate response column.

- If Alternative 1 was chosen for the product(s), complete sections A, B and C.
- If Alternative 2 using a PLT (choice 1) was chosen for the product(s), complete sections A and C only.
- If Alternative 2 using an AMAP (choice 2) was chosen for the product(s), complete sections B and C only
- If Alternative 3 was chosen for the product(s), complete section C only

(NOTE: Review establishment HACCP plan, Sanitation program or prerequisite program depending on the Alternative chosen for the product. If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Score responses using the scoring instructions at the end of these questions.)

A. Post-lethality Treatment (for Alternative 1, and Alternative 2 using PLT)

Questions	Yes	No	Not Sure	N/A
1. Is the PLT validation conclusively adequate (from SECTION I and Table 1)				
2. Are CCPs, CLs or critical variables for the PLT reassessed, reevaluated or verified regularly or as needed?				
3. Is recurrence of positive product or FCS controlled at zero or prevented? *(Note: If there is no positive product or FCS, place an X on N/A)*				
4. Are corrective actions conducted when CCP is not achieved?				
5. Are corrective actions conducted if positive products or positive FCS are found?				
6. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
7. Was the last Food Safety Assessment for the establishment conducted prior to implementation of the rule in October 2003? *(Note: If FSA was conducted after10/2003 and the purpose is not for Listeria rule non-compliance or positives; OR, if no FSA has ever been conducted, place an X on N/A.).*				

Questions	Yes	No	Not Sure	N/A
8. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please score for PLT (Table 4).

B. Antimicrobial Agent or Processes (for Alternative 1, and Alternative 2 using AMAP)

Questions	Yes	No	Not Sure	N/A
1. Is the validation/effectiveness of AMAP conclusively adequate (from SECTION II and Table 2)?				
2. Are the CCPs, CLs (if AMAP is in the HACCP plan) or critical variables (if AMAP is in the SSOP or Prerequisite Programs) reassessed, reevaluated or verified regularly or as needed?				
3. Is the recurrence of positive product or FCS controlled at zero or prevented? *(Note: If there is no positive product or FCS, place an X on N/A)*				
4. Are corrective actions conducted when the CCP or critical values are not achieved?				
5. Are corrective actions conducted if positive products or positive FCS are found? *(Note: If there is no positive product or FCS, place an X on N/A)*				
6. Does the labeling of product shelf life agree with the shelf life determined from the AMAP study or model? (*Note: If the label does not indicate a shelf life ,place an X on N/A.)*				
7. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
8. Was the last Food Safety Assessment for the establishment conducted prior to implementation of the rule in October 2003? *(Note: The FSA should only be for Listeria rule non-compliance or positives. If no assessment has ever been conducted, place an X on N/A.)*				
9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please score for AMAP (Table 4).

C. Sanitation Program (for Alternative 1, Alternative 2 and Alternative 3)

Questions	Yes	No	Not Sure	N/A
1. Is the effectiveness of the sanitation program conclusively adequate (from SECTION III and Table 3)				
2. Is the establishment following the sanitizing procedures as stated in its Sanitation SOP or prerequisite programs?				
3. Is recurrence of positive product or FCS controlled at zero or prevented? *(Note: If there is no positive product or FCS, place an X on N/A)*				
4. Does the establishment follow procedures for taking at least the minimum number of samples at designated areas for FCS testing as described in its control program?				
5. Are sanitation corrective actions conducted promptly and effectively, e.g., when product or FCS tests positive?				
6. Does the establishment persist or succeed in determining the cause and source of the positive result? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
7. Does the establishment use more rigorous sanitizing to prevent recurrence of positives? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
8. Was the last Food Safety Assessment for the establishment conducted prior to implementation of the rule in October 2003? *(Note: The FSA should only be for Listeria rule non-compliance or positives. If no assessment has ever been conducted, place an X on N/A.)*				
9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please score for Sanitation (Table4).

Scores:
Conclusive: Answered 'yes' to all (can be N/A for 7- 8 (A), and 8-9 (B and C)
Substantiated: Answered 'yes' to 1-2 and 'yes' or 'N/A' to all remaining questions
Inconclusive: Answers with 'no' or' not sure' to 1-5 for A and C; 1-6 for B

Table 4. Features of an on-going verification system

Use the scores obtained from the questions above to establishment PLT, AMAP or Sanitation program as applicable**, and circle the score provided (in parenthesis)** .

Control measure	Feature	Criteria	Inconclusive[1]	Substantiated[1]	Conclusive[1]
On-going verification system	Post-lethality treatment		(0)	(5)	(10)
	Antimicrobial agent or process		(0)	(5)	(10)
	Sanitation program		(0)	(5)	(10)

[1] Number in parenthesis is the possible maximum score

Add scores for PLT, AMAP or Sanitation depending on the control program that the establishment has.

APPENDIX

DEFINITION/EXPLANATION OF TERMS

Antimicrobial Agent
A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as LM, or that has the effect of suppressing or limiting growth of a pathogen such as LM in the product throughout the shelf life of the product (9 CFR430.1). Examples: potassium lactate, sodium diacetate, which limit the growth of LM.

Antimicrobial Process
An operation, such as freezing that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as LM, in the product throughout the shelf life of the product, (9CFR 430.1). Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth.

Challenge Study
A study that documents the adequacy of control measures in a process. This involves inoculating the target organism (e.g., LM) into a product to determine the effect of control measures such as post-lethality treatment or antimicrobial agent or process on the reduction or growth of the organism. Challenge studies are usually performed in a laboratory to avoid the possible spread of contamination in an establishment. They are also performed under laboratory conditions, which means that the scale of the study is adjusted, based on the capacity of the laboratory (i.e. fewer products may be tested, and a water bath may be used rather than a hot-water pasteurizer). The number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The study determines the effect using different processing variables such as time, temperature, pressure, concentration, acidity, pH and others. If challenge studies are used as supporting documentation by the establishment, it is important that they use product that has similar physical characteristics to that being produced by the establishment (i.e., pH, Aw, etc.) and processing (and intervention) steps that are similar to those utilized by the establishment. For example, for a post-lethality treatment like steam pasteurization or hot water pasteurization, the time and temperature of treatment similar to that used for the product itself may be critical components of a challenge study. For high pressure pasteurization, pressure is a critical variable. For the use of chemical additives as antimicrobial agents, pH, acidity, and concentration may be additional critical variables.
Challenge studies used for validation may or may not be published in scientific journals, and can be 1) conducted for any product; 2) conducted for an establishment's specific product or processing; or 3) conducted by the manufacturer of an equipment or chemical additive for use in the processing of a product. Challenge studies conducted for an establishment's specific product or a manufacturer's equipment or chemical additives have the advantage of using the same formulation, procedure and critical factors of moisture, pH, time, temperature, pressure, etc. as those used in the establishment. However, most of these challenge studies are not published. Published studies have the advantage of being peer-reviewed before publication, but may not be specific for an establishment's product or processing.

Microbial Pathogen Computer Modeling (MCPM) Program
A modeling program is a mathematical model describing the growth characteristics of pathogens in foods subjected to different environmental (intrinsic factors such as pH, salt, phosphates, nitrites, and water activity, and extrinsic factors such as temperature and culture atmosphere) and processing conditions. Computer-based microbial modeling programs may be used to provide an estimate of the influence of each limiting agent or combination of agents during processing. A computer model is a predictive tool and must be evaluated in terms of relevance and validity to the product in question. An establishment should verify the model's predictions for the establishment's product and conditions of processing by conducting tests, such of product and food contact surfaces, to confirm whether conditions are adequately controlled, as predicted. Of note, some modeling programs may identify zero growth as allowing up to 1 log growth, as a consequence of measurement error. Establishments should be aware of this when relying upon such assumptions.

Products Covered by 9 CFR 430
All post-lethality exposed RTE meat and poultry
Examples: deli meat, hot dog, jerky, chicken nuggets

Products Not Covered by 9 CFR 430
Cook-in bag and shipped products
Hot-filled products
Partially cooked products
Commercially sterile, thermally processed products

Post-lethality Exposed Product
Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment (9 CFR 430.1). Examples of post-lethality exposed products: hot dogs after the casings are removed; cooked roast beef after removing the cooking bag.

Post lethality Processing Environment
The area in an establishment into which product is routed after having been subjected to an initial lethality treatment (CFR 430.1). Examples are the production area where hotdog casings are peeled, or products are sliced and re-bagged.

Post-lethality Treatment (PLT)
A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1). Examples: hot water pasteurization, steam pasteurization, high pressure processing.

Pre-packaging Post-lethality Treatment
This is a post-lethality treatment that is conducted prior to packaging. Most PLT are conducted after the product is repackaged. Because the PLT is applied before packaging, the product can be exposed to re-contamination after the treatment. The establishment has to include methods to demonstrate, with high confidence, that recontamination does not occur. Some of the methods

include placing packaging right after the treatment by physically placing the packaging equipment next to the treatment equipment, having aseptic environmental controls, including micro-filtered air flow and positive/negative air pressure, as well as mechanisms for ensuring equipment does not become contaminated within the packaging room.

Published Study
A challenge or inoculated pack study conducted by scientists, subsequently reviewed by other scientists knowledgeable in the subject (peer-reviewed), before publishing in a scientific journal.

Shelf life Study
A shelf life study is one that measures the increase or decrease in the number of the target organism or pathogen during storage. For an antimicrobial agent or process (AMAP), a shelf life study is important because it determines the time (in days) at a slightly abusive refrigerated storage temperature (e.g., at 45 degrees Fahrenheit) that the number of LM increases, signifying growth. A slightly abusive temperature is used in order to ensure that if LM is present and viable, growth will occur and can be measured throughout shelf-life. This slightly abusive temperature also represents the worse-case conditions that could occur during cold-chain storage and handling.

Validation
Validation is a process of demonstrating that the HACCP system, if operated as designed, can adequately control identified hazards to produce a safe product. Validation consists of a scientific or technical justification or documentation of control, and an initial demonstration proving that the system will perform as expected. Validation can be derived from a challenge study, a published study from a peer-reviewed scientific journal, modeling program, data underlying published guidelines, or establishment data.
The documentation must identify the hazard and the pathogen, including the level of hazard prevention or pathogen reduction to be achieved, and all associated factors or conditions should identify which processing steps will achieve the specified reduction or prevention, and how these processing steps will be monitored. The scientific or technical basis should be related to the specific hazard or pathogen and should identify specific control parameters. The demonstration should be conducted in the plant using the parameters in the validation. As part of the demonstration, the establishment should observe, measure, and record results and should show that the plant can routinely meet the parameters in order to control the hazards.

EXAMPLES OF CHALLENGE STUDIES

When faced with a challenge study on file to document validation, it is important to look at the title and the abstract or summary first. The abstract at the beginning of the document always give the most important findings of the study. Look for the objective, the procedure or conditions used and the results. Sometimes the equipment used is also included in the abstract. The abstract usually gives the critical factors (e.g., time, temperature, pH, concentration, pressure), the initial level of pathogens or organisms and how these factors affected the level of pathogens or organisms, and whether there was reduction, suppression or no effect. For important information not found in the abstract, look or read the other sections of the document. The Materials and

Methods section includes the microorganisms used and microbial inoculation method, post-lethality treatment procedure, and data analysis. The Results and Discussion section gives the results, tables, graphs, pictures, and the authors' explanation and discussion of the results. The Conclusions section gives the overall result of the study, conclusions based on the conditions of the study and recommendations. Sometimes the conclusions are included in the end of the Results and Discussions section.

The following are summaries of challenge studies for post-lethality treatment and antimicrobial agents taken from the Compliance Guidelines for the *Listeria* rule (FSIS website). The summaries include the conditions for post-lethality treatments or addition of antimicrobial agents and the resulting time, temperature pressure or concentration to control *L. monocytogenes*. The critical variables of time, temperature, pressure, concentration or pH, as well as the procedure or equipment that are bolded are the important information that needs to be determined when reading or scanning a challenge study. These variables are the ones used for the CCP and critical limit. Noting down the information gathered from the abstract or summary as shown for the first challenge study would help in determining if the establishment is using the same or similar procedure, equipment and critical factors as the challenge study.

A. Steam Pasteurization and Hot Water Pasteurization
(Important information for validation are bolded)

Studies by Murphy et al. (2003) showed that **post-cook hot water pasteurization and steam pasteurization** resulted in a **7 $\log_{10}$ reduction of *L. monocytogenes*** in surface inoculated vacuum packaged fully cooked chicken fillets and strips. The reduction was effective when **single –packaged breast fillets, 227 g- packaged strips and 454 g-packaged strips** were **heat treated at 90° C** in a **pilot-scale steam cooker or hot water cooker for 5, 25 and 35 minutes, respectively.**

Information gathered from the summary or abstract:
Post-lethality treatment: hot water pasteurization or steam pasteurization
Products: fully cooked chicken breast fillets and strips
Procedure: fully cooked products were surface inoculated with *L. monocytogenes*, vacuum packaged and pasteurized
Equipment used for the pasteurization treatment:
Steam pasteurization: pilot-scale steam cooker
Hot water pasteurization: pilot-scale hot water cooker
Temperature of pasteurization: 90 C
Reduction of *L. monocytogenes*: 7 log reduction
Products and time of pasteurization that resulted in 7 log reduction

Product	**Time of pasteurization (min)**
Single-packaged breast fillets	5
227g-package strips	25
454 g-packaged strips	35

Murphy, R.Y., L. K. Duncan, K.H. Driscoll, B.L. Beard, M. E. Berrang and J.A. Marcy. 2003. Determination of thermal lethality of *Listeria monocytogenes* in fully cooked chicken breast fillets and strips during post cook in-package pasteurization J. Food Protect 66:578-583.

B. High Hydrostatic Pressure Processing
(Important information for validation are bolded)

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating ***L. monocytogenes*** **in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions.** Results show that an inoculum of about **10^4 *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34° F.** There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. **According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.**

Raghubeer, E.V. and E.D. Ting. 2003. The Effects of high hydrostatic pressure (HPP) on *Listeria monocytogenes* in RTE meat products. Avure Technologies, Inc. Submitted for publication.

C. Studies on the Use of Antimicrobial Agents
(Important information for validation are bolded)

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. **Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm^2 of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days.** Results are as follows:

ANTIMICROBIAL	**LEVEL (%)**	***L. MONOCYTOGENES* GROWTH INHIBITION**
Sodium lactate	**3**	**70 days no pathogen growth**
Sodium diacetate	**0.25**	**50 days no pathogen growth**
Sodium acetate	**0.25, 0.50**	**20 days no pathogen growth**
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	**0.5**	**120 days no growth and reduced pathogen growth**
Inoc. Control	**0.0**	**Increased to 6 logs in 20 days**

Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

No pathogen growth refers to zero increase in the number of inoculated *L. monocytogenes* cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Levels of sodium lactate at 6.0 %

and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.

Bedie, B. K., J. Samelis, J.N. Sofos, K. E. Belk, J. A. Scanga, and G. C. Smith . 2001. Antimicrobials in the formulation to control *Listeria monocytogenes* postprocessing contamination on frankfurters stored at 4° C in vacuum packages. J. Food Protect. 64:1949-1955

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and **frankfurter formulations** as the previous study described above. However, in this study **combinations of antimicrobials were used, and in combination with hot water treatment. Therefore this is a combination of post-lethality treatment and antimicrobial agent. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C** shows:

TREATMENT	**LEVELS (%)**	***L. MONOCYTOGENES* GROWTH INHIBITION**
Sodium lactate	**1.8**	**35-50 days no growth**
Sodium lactate + sodium acetate	**1.8 0.25**	**120 days no growth; 35-50 days growth reduction**
Sodium lactate + Sodium diacetate	**1.8 0.25**	**120 days no growth; 35-50 days growth reduction**
Sodium lactate + Glucuno-delta-lactone	**1.8 0.25**	**120 days no growth, 35-50 days growth reduction**
Hot water treatment (80° C, 60 s) + Sodium lactate	**1.8**	**Inoc. population reduced by 0.4-0.9 log CFU/cm^2 , and 50-70 days growth reduction by 1.1-1.4 CFU/ cm^2**
Hot water treatment (80° C, 60 s)		**Increase in growth to about 6-8 logs in 50 days**
Inoculated Control, no treatment		**Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days**

Note: **Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution**. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

Samelis, J. G.K. Bedie, J.N. Sofos, K.E. Belk, J.A. Scanga, and G.C. Smith. 2002. Control of *Listeria monocytogenes* with combined antimicrobials after postprocess contamination and extended storage of frankfurters at 4° C in vacuum packages. J. Food Protect. 65: 299-307.